



The Division of Drug Information (DDI) is CDER's focal point for public inquiries. We serve the public by providing information on human drug products and drug product regulation by FDA.

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The U.S. Food and Drug Administration (FDA) is investigating the use of the pain medicine tramadol in children aged 17 years and younger, because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in children treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. We are evaluating all available information and will communicate our final conclusions and recommendations to the public when our review is complete.

Tramadol is not FDA-approved for use in children; however, data show it is being used “off-label” in the pediatric population. Health care professionals should be aware of this and consider prescribing alternative FDA-approved pain medicines for children.

Parents and caregivers of children taking tramadol who notice any signs of slow or shallow breathing, difficult or noisy breathing, confusion, or unusual sleepiness should stop tramadol and seek medical attention immediately by taking their child to the emergency room or calling 911. Parents and caregivers should talk with their child’s health care professional if they have any questions or concerns about tramadol or other pain medicines their child is taking.

For more information, please visit: [tramadol](#).